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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,344	12/30/2003	Jerome B. Zeldis	9516-070-999 (CAM No.:501	8197

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,344	ZELDIS, JEROME B.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *5 and 6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time amendment and remarks filed 11/30/07. Claims 1, 16 and 17 are amended. Claims 1-27 are pending.

Previous rejections/objections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 7-17, 22, 23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al. (WO 01/57022, provided by applicant on form 1449 filed 11/30/07).

Green discloses pyrazole compounds such as those of formula I or II in compositions (page 34, lines 23-29) for treating JNK mediated conditions (page 37, lines 31-34), the JNK mediated conditions are listed on page 38, lines 3-30 and included in the list are cardiovascular conditions such as heart attack, myocardial infarction and congestive heart failure and rheumatoid arthritis (page 38, lines 16, 18 and 19). Pharmaceutically acceptable carriers for the composition and meeting the limitation of claim 7 are listed on page 41, lines 19-33. While treatment regimen for any particular patient would depend on a number of factors (page 45, lines 12-21), Green's composition could be formulated into implantable devices, namely coated devices such as prostheses, artificial valves, vascular grafts, stents and catheters (page 45, lines

24-34), with these implantable devices meeting the requirements of claims 8, 13, 22 and 23. The coating composition comprises polymers such as polylactic acid, polyethylene glycol, polycaprolactone (page 46, lines 1-8), the lactic and caprolactone polymers meeting the requirements of claims 9 and 10. Green discloses that the coatings are optionally further covered by suitable topcoat polymer that singly or in combination provide controlled release of the actives (page 46, lines 5-9) thereby meeting claim 11 and claim 14 is met because effective amount is any amount. The coating of the medical devices as stated above meets the method of claims 12 and 15. One aspect of Green is to administer the composition (page 31, lines 25 and 26 for treating the treatable conditions listed on page 38, lines 3-30; page 33, lines 1-5) meeting claim 17.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4 and 7-27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bhagwat et al. (US 2002/0103229) in view of Chudzik et al. (US 2002/0188037) for reasons of record and reiterated herein below.

Bhagwat describes method for treating conditions responsive to JNK inhibition by administering pharmaceutical compositions containing any of the compounds and pharmaceutically acceptable carrier (Claim 22; paragraph [0015]). Compounds numbers 243 at para. [1145] and 272 at para. [1320] is the elected compound. Some of the conditions treatable are restenosis following angioplasty, organ transplantation (para. [0017]) and the product can be implanted (para. [0127]). The carrier meets claims 7. Compound #s 243 and 272 meet the limitations of the JNK inhibitors of the claims. The surgical intervention in angioplasty meets claims 16-26 except that although the composition of the Bhagwat is implanted, there is no specific disclosure for stents. While the compounds of Bhagwat are delivered in a controlled release of sustained release delivery (para. [0131], [0133] and [0135], Bhagwat is silent on the polymers that lends process to the release profile. However, it is known in the art that polymers such as acrylate polymers are used as sustained release coating carriers. For example, Chudzik discloses acrylate coated stents that provide controlled release of active agents (abstract, para. [0091] and claim 30). Regarding claim 27, compositions are known to be held in containers/kits for ease of handling and a kit is an obvious storage/holding facility for drug compositions. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use coated stent for the sustained delivery of compounds 243 and 272 of Bhagwat.

Response to Arguments

5. Applicant's arguments filed 11/30/07 have been fully considered but they are not persuasive.

6. Applicant argues that the fact that Bhagwat uses compounds of the pending method claims in implantable composition in a broad disclosure "does not provide the requisite reason

for one of ordinary skill in the art to use the compounds with a stent," so that applicant contends that there is no reason why one of ordinary skill in the art would prepare a stent containing the compound of the claimed method. Applicant says that there is no articulated reasoning with rational underpinning support for the legal conclusion of obviousness according to In re Kahn and as supported by KSR.

7. **Response**:

8. Firstly, it is noted that the rejection was made over two references and the rationale for the rejection is as stated on record in the rejections. Secondly, applicant's argument is directed to one reference, the Bhagwat reference, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Thirdly, the examiner agrees with applicant that a stent is a medical device so also is an implantable device such as disclosed by Bhagwat. But although, Bhagwat did not specifically use the term stent, Bhagwat specifically contemplates implanting the composition and stents are implants; and fourthly, stents are known implantable devices as evidenced by claims 5 and 14 of US 6,206,835 so that the ordinary skilled artisan would have reasonable expectation of success that the an implantable device such as a stent would deliver the composition of Bhagwat for anticipated treatment of restenosis following angioplasty. Furthermore, the secondary reference of Chudzik was cited to show acrylate coated stents providing controlled release of active agents (abstract, para. [0091] and claim 30). Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable

expectation of success that the coated stent would successfully be used to deliver the implantable composition of Bhagwat for the anticipated treatment of restenosis.

9. Claims 1, 16-21 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (WO 01/57022, provided by applicant on form 1449 filed 11/30/07) in view of Hariharan et al. ("Can Stent-Angioplasty Be a Valid Alternative to Surgery When Revascularization Is Indicated for Anomalous Origination of a Coronary Artery from the Opposite Sinus?" in Tex Heart Inst J. 2002; 29(4): 308-313) or Treating Heart, blood Vessels and Circulation, Cleveland Clinic Heart Center, Sept. 18, 2002.

10. Green is described above under 35 USC 102 as anticipating claims 1-3, 7-17, 22 and 23. While Green contemplates implantation, Green is silent on whether the implantation is surgical. Regarding claim 27, compositions are known to be held in containers/kits for ease of handling and a kit is an obvious storage/holding facility for drug compositions. However, it is known in the art that stents and other medical devices can be surgically implanted. For example, it is known that stenting can be done non-surgically (the Cleveland heart clinic, on page 1 of the 4 pages) and also surgically (Hariharan, pp. 308-313). Therefore, taking the teaching of the references together, the ordinary skilled artisan at the time the invention was made would have reasonable expectation of success in surgically or non surgically implanting the medical device/stent of Green for the contemplated delivery of the composition of Green for treating conditions such as myocardial infarction.

No claim is allowed.

11. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 11/30/07 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618